

03-06-06

IFW



**EXPRESS MAIL NO.: EV452776966US**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Jerome B. Zeldis

Confirmation No.: 9742

Application No: 10/534,324

Group Art Unit: To Be Assigned

Filed: May 5, 2005

Examiner: To Be Assigned.

For: METHODS OF USING AND  
COMPOSITIONS COMPRISING SELECTIVE  
CYTOKINE INHIBITORY DRUGS FOR THE  
TREATMENT AND MANAGEMENT OF  
MYELOPROLIFERATIVE DISEASES

Jones Day Docket No.: 9516-086-999  
(CAM No.: 501872-999085)

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. §1.56 AND §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and §1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Applicant hereby directs the Examiner's attention to References **A01-A66, B01-B08** and **C01-C45**, listed on the attached Substitute For form 1449/PTO entitled "Information Disclosure Statement by Applicant."

Copies of references B01-B08 and C01-C45 are submitted herewith. Copies of References A01-A65, being U.S. patents and U.S. publication documents are not submitted herewith pursuant to 37 C.F.R. § 1.98(a)(2)(ii). A copy of Reference A65, being a provisional application that is available at the USPTO's private PAIR system is not submitted herewith pursuant to 1287 OG 163.

Identification of the listed references is not to be construed an admission of Applicant or Attorneys for Applicant that such references are available as "prior art" against the subject application. Applicant respectfully requests that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

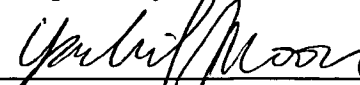
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./

NYJD: 1613884.1

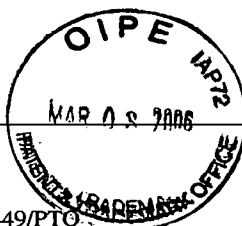
This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the mailing of the first Office action on the merits. Therefore, no fee is believed to be due. Should any fee be required, however, please charge such fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: March 3, 2006

  
\_\_\_\_\_  
Yeahsil Moon (Reg. No.) 52,042  
For: Anthony M. Insogna 35,203  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, New York 10017  
(212) 790-9090

Enclosures



Substitute for Form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT  
(Use several sheets if necessary)

ATTY DOCKET NO.  
9516-086-999  
(CAM No. 501872-999085)

APPLICATION NO.  
10/534,324

APPLICANT:  
Zeldis

FILING DATE:  
May 5, 2005

ART UNIT: CONF. NO.:  
9742

### U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS*		DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A01	3,536,809	10/27/1970	Applezweig	
	A02	3,598,123	08/10/1971	Zaffaroni	
	A03	3,845,770	11/05/1974	Theeuwes et al.	
	A04	3,916,899	11/04/1975	Theeuwes et al.	
	A05	4,008,719	02/22/1977	Theeuwes et al.	
	A06	5,059,595	10/22/1991	La Grazie	
	A07	5,073,543	12/17/1991	Marshall et al.	
	A08	5,120,548	06/09/1992	McClelland et al.	
	A09	5,354,556	10/11/1994	Sparks et al.	
	A10	5,463,063	10/31/1995	Muller	
	A11	5,591,767	01/07/1997	Mohr et al.	
	A12	5,605,914	02/25/1997	Muller	
	A13	5,632,984	05/27/1997	Wong et al.	
	A14	5,639,476	06/17/1997	Oshlack et al.	
	A15	5,643,915	07/01/1997	Andrulis, Jr. et al.	
	A16	5,658,940	08/19/1997	Muller et al.	
	A17	5,674,533	10/07/1997	Santus et al.	
	A18	5,698,579	12/16/1997	Muller.	
	A19	5,703,098	12/30/1997	Muller	
	A20	5,728,844	03/17/1998	Muller	
	A21	5,728,845	03/17/1998	Muller	
	A22	5,733,566	03/31/1998	Lewis	
	A23	5,736,570	04/07/1998	Muller	
	A24	5,770,589	06/23/1998	Billson	
	A25	5,801,195	09/01/1998	Muller et al.	
	A26	5,877,200	03/02/1999	Muller	
	A27	5,929,117	07/27/1999	Muller et al.	
	A28	5,968,945	10/19/1999	Muller et al.	
	A29	6,001,368	12/14/1999	Jenks	

EXAMINER

/Marcos Sznaidman/

DATE CONSIDERED

10/27/2008

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. M.S./

Substitute for Form 1449/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO. 9516-086-999 (CAM No. 501872-999085)	APPLICATION NO. 10/534,324
	APPLICANT: Zelfdis	
	FILING DATE: May 5, 2005	ART UNIT:    CONF. NO.: 9742

### U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS*		DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A30	6,011,050	01/04/2000	Muller et al.	
	A31	6,015,803	01/18/2000	Wirostko	
	A32	6,020,358	01/04/2000	Muller et al.	
	A33	6,046,221	04/04/2000	Muller et al.	
	A34	6,075,041	06/13/2000	Muller	
	A35	6,130,226	10/10/2000	Muller et al.	
	A36	6,180,644	01/30/2001	Muller et al.	
	A37	6,200,987	03/13/2001	Muller	
	A38	6,214,857	04/10/2001	Muller et al.	
	A39	6,218,369	04/17/2001	Bombardelli et al.	
	A40	6,225,348	05/01/2001	Paulson	
	A41	6,262,101	07/17/2001	Muller et al.	
	A42	6,281,230	08/28/2001	Muller et al.	
	A43	6,284,780	09/04/2001	Muller et al.	
	A44	6,316,471	11/13/2001	Muller et al.	
	A45	6,326,388	12/04/2001	Man et al.	
	A46	6,429,221	08/06/2002	Muller et al.	
	A47	6,479,554	11/12/2002	Muller et al.	
	A48	6,518,281	02/11/2003	Muller et al.	
	A49	6,656,964	12/02/2003	Muller et al.	
	A50	6,667,316	12/23/2004	Man et al.	
	A51	6,844,359	01/18/2005	Muller et al.	
	A52	6,699,899	03/02/2004	Man et al.	
	A53	6,911,464	06/28/2005	Man et al.	
	A54	6,962,940	11/08/2005	Muller et al.	
	A55	2003-0045726	03/06/2003	Muller et al.	
	A56	2003-0114516	06/19/2003	Muller et al.	
	A57	2004-0006096	01/08/2004	Muller et al.	
	A58	2004-0019106	01/29/2004	Muller et al.	

<b>EXAMINER</b> /Marcos Sznaidman/	<b>DATE CONSIDERED</b> 10/27/2008
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. NY 10013 M.S./

Substitute for Form 1449/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO. 9516-086-999 (CAM No. 501872-999085)	APPLICATION NO. 10/534,324
	APPLICANT: Zelfdis	
	FILING DATE: May 5, 2005	ART UNIT:      CONF. NO.: 9742

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS*		DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A59	2004-0147588	07/29/2004	Man et al.	
	A60	2004-0167174	08/26/2004	Man et al.	
	A61	2004-0167199	08/26/2004	Muller et al.	
	A62	2004-0204448	10/14/2004	Muller et al.	
	A63	2004-0254214	12/16/2004	Man et al.	
	A64	2005-0014727	01/20/2005	Muller et al.	
	A65	2006-0025457	02/02/2006	Muller et al.	
	A66	60/372,348	04/02/2002	Hariri et al.	

## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS*		Country Code, Number, Kind of Code (if known)	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
						YES	NO
	B01	WO 95/01348	01/12/1995	Celgene Corporation			
	B02	WO 97/08143	03/06/1997	Celgene Corporation			
	B03	WO 97/23457	07/31/1997	Celgene Corporation			
	B04	WO 99/06041	02/11/1999	Celgene Corporation			
	B05	WO 01/34606	05/17/2001	Celgene Corporation			
	B06	WO 01/45702	06/28/2001	Celgene Corporation			
	B07	WO 03/080048	10/02/2003	Celgene Corporation			
	B08	WO 03/080049	10/02/2003	Celgene Corporation			

EXAMINER'S INITIALS*	NON PATENT LITERATURE DOCUMENTS (include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, etc.), date, page(s), volume, publisher, city and/or country where published., etc.)	
	C01	BAROSI et al., 2001, "Safety and efficacy of thalidomide in patients with myelofibrosis with myeloid metaplasia," <i>Br. J. Haematol.</i> 114(1):78-83
	C02	BENNETT AND PLUM, eds., 1996, <i>Cecil Textbook of Medicine</i> , 20 <sup>th</sup> edition, W.B. Saunders Company, pp. 502-503, 922-925
	C03	BRAUNWALD et al., eds., 2001, <i>Harrison's Principles of Internal Medicine</i> , 15 <sup>th</sup> edition, McGraw-Hill, pp. 701-703
	C04	CANEPA et al., 2001, "Antitumor activity of thalidomide in idiopathic myelofibrosis," <i>Haematologica</i> 86(11 Suppl 1):12-14

EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	10/27/2008
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. NY 10013 M.S./

Substitute for Form 1449/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO. 9516-086-999 (CAM No. 501872-999085)	APPLICATION NO. 10/534,324
	APPLICANT: Zelfdis	
	FILING DATE: May 5, 2005	ART UNIT:    CONF. NO.: 9742

EXAMINER'S INITIALS*	NON PATENT LITERATURE DOCUMENTS (include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, etc.), date, page(s), volume, publisher, city and/or country where published., etc.)
C05	CANEPA et al., 2001, "Thalidomide in agnogenic and secondary myelofibrosis," <i>Br. J. Haematol.</i> 115(2):313-315
C06	CORRAL, L.G. et al., 1999, "Immunomodulation by thalidomide and thalidomide analogues," <i>Ann. Rheum. Dis.</i> 58:(Suppl I)1107-1113
C07	COSTA et al., 1998, "Thalidomide (TLD) and pentoxifylline (FTX) prevent the develeopment of chronic cardiomyopathy provoked by doxorubicin (DXR) in rats without inhibiting its anti-tumoral effect," <i>Blood</i> 92(10 Suppl. 1):235b, Abstract 4007
C08	DALEY et al., 1990, "Induction of chronic myelogenous leukemia in mice by the P210 <sup>bcr/abl</sup> gene of the Philadelphia chromosome," <i>Science</i> 247(4944):824-830
C09	D'AMATO et al., 1994, "Thalidomide is an inhibitor of angiogenesis," <i>PNAS USA</i> 91:4082-4085
C10	DREDGE et al., 2003, "Angiogenesis inhibitors in cancer therapy," <i>Curr. Opin. Investig. Drugs</i> 4(6):667-673
C11	DREDGE et al., 2002, "Immunological effects of thalidomide and its chemical and functional analogs," <i>Crit. Rev. Immunol.</i> 22(5-6):425-437
C12	DREDGE et al., 2002, "Recent developments in antiangiogenic therapy," <i>Expert Opin. Biol. Ther.</i> 2(8):953-966
C13	EHRENPREIS et al., 1999, "Thalidomide therapy for patients with refractory Crohn's disease: an open-label trial," <i>Gastroenterology</i> 117(6):1271-1277
C14	GEE et al., 2003, "Selective cytokine inhibitory drugs with enhanced antiangiogenic activity control tumor growth through vascular inhibition," <i>Cancer Res.</i> 63(23):8073-8078
C15	HAO et al., 2000, " Expression of interferon consensus sequence binding protein (ICSBP) is downregulated in Bcr-Abl-induced murine chronic myelogenous leukemia-like disease, and forced coexpression of ICSBP inhibits Bcr-Abl-induced myeloproliferative disorder," <i>Mol. Cell. Biol.</i> 20(4):1149-1161
C16	HIDESHIMA et al., 2000, "Thalidomide and its analogs overcome drug resistance of human multiple myeloma cells to conventional therapy," <i>Blood</i> 96(9):2943-2950
C17	KOCH, 1985, "Thalidomide and congeners as anti-inflammatory agents," <i>Prog. Med. Chem.</i> 22:165-242
C18	KROPFF, 2000, <i>Blood</i> 96(11 part 1):168a, Abstract 725
C19	KURZROCK et al., 1988, "The molecular genetics of Philadelphia chromosome-positive leukemias," <i>N. Engl. J. Med.</i> 319(15):990-998
C20	LUNDBERG et al., 2000, "Bone marrow in polycythemia vera, chronic myelocytic leukemia, and myelofibrosis has an increased vascularity," <i>Am. J. Pathol.</i> 157(1):15-19
C21	MARRIOTT et al., 1998, " CC-3052: a water-soluble analog of thalidomide and potent inhibitor of activation-induced TNF-alpha production," <i>J. Immunol.</i> 161(8):4236-4243
C22	MARRIOTT et al., 2001, "Immunotherapeutic and antitumour potential of thalidomide analogues," <i>Expert Opin. Biol. Ther.</i> 1(4):1-8
C23	MARRIOTT et al., 2002, "Thalidomide and its analogues have distinct and opposing effects on TNF-alpha and TNFR2 during co-stimulation of both CD4(+) and CD8(+) T cells," <i>Clin. Exp. Immunol.</i> 130(1):75-84
C24	MARRIOTT et al., 2003, " Thalidomide derived immunomodulatory drugs (IMiDs) as potential therapeutic agents," <i>Curr. Drug Targets-Immune Endocr. Metabol. Disord.</i> 3(3):181-186
C25	MARTYRE, 1991, "Platelet PDGF and TGF-beta levels in myeloproliferative disorders," <i>Leuk. Lymphoma</i> 6(1):1-6
C26	MARX et al., 1999, "A phase I/II trial of thalidomide as an antiangiogenic agent in the treatment of advanced cancer," <i>Proc. Am. Soc. Clin.Oncol.</i> 18:454a

EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	10/27/2008
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

Substitute for Form 1449/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO. 9516-086-999 (CAM No. 501872-999085)	APPLICATION NO. 10/534,324
	APPLICANT: Zelfdis	
	FILING DATE: May 5, 2005	ART UNIT:      CONF. NO.: 9742

EXAMINER'S INITIALS*	NON PATENT LITERATURE DOCUMENTS (include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, etc.), date, page(s), volume, publisher, city and/or country where published., etc.)
	C27 McCANN, 1999, "Results of breast cancer drugs under spotlight," <i>Drug Topics</i> 41-42
	C28 MOLLER et al., 1997, "Inhibition of IL-12 production by thalidomide," <i>J. Immunol.</i> 159(10):5157-5161
	C29 MULLER et al., 1999, "Amino-substituted thalidomide analogs: potent inhibitors of TNF-alpha production," <i>Bioorg. Med. Chem. Lett.</i> 9(11):1625-1630
	C30 MULLER et al., 1996, "Structural modifications of thalidomide produce analogs with enhanced tumor necrosis factor inhibitory activity," <i>J. Med. Chem.</i> 39(17):3238-3240
	C31 MULLER et al., 1998, "Thalidomide analogs and PDE4 inhibition," <i>Bioorg. Med. Chem. Lett.</i> 8(19):2669-2674
	C32 MUNSHI et al., 1999, "Peripheral blood stem cell, collection (FBSC) after CAD + G-CSF as part of total therapy II in newly diagnosed multiple myeloma (MM): Influence of thalidomide (THAL) administration," <i>Blood</i> 94(10 part 1):578a, Abstract 2577
	C33 PRUNERI et al., 1999, "Angiogenesis in myelodysplastic syndromes," <i>Br. J. Cancer</i> 81(8):1398-401
	C34 RAJKUMAR, 2000, "Thalidomide in multiple myeloma," <i>Oncology</i> (Williston Park) 14(12 Suppl 13):11-16
	C35 RAZA et al., 2001, "Thalidomide produces transfusion independence in long-standing refractory anemias of patients with myelodysplastic syndromes," <i>Blood</i> 98(4):958-965
	C36 SCHANDENÉ et al., 2000, "Interferon alpha prevents spontaneous apoptosis of clonal Th2 cells associated with chronic hypereosinophilia," <i>Blood</i> 96(13):4285-4292
	C37 SILVER, 1993, "Interferon-alpha 2b. A new treatment for polycythemia vera," <i>Annals Int. Med.</i> 119(11):1091-1092
	C38 SINGHAL et al., 1999, "Antitumor activity of thalidomide in refractory multiple myeloma," <i>N. Engl. J. Med.</i> 341(21):1565-1571
	C39 TEFFERI et al., 1994, "Issues in the diagnosis and management of essential thrombocythemia," <i>Mayo Clin. Proc.</i> 69(7):651-655
	C40 TIERNEY et al., eds., 1998, <i>Current Medical Diagnosis and Treatment</i> , 37 <sup>th</sup> edition, Appleton & Lange, pp. 499-503
	C41 VACCA et al., 2001, "Angiogenesis in hematologic malignancies," <i>Haematol.</i> 86(11 Suppl 1):1-5
	C42 VASILIAUSKAS et al., 1999, "An open-label pilot study of low-dose thalidomide in chronically active, steroid-dependent Crohn's disease," <i>Gastroenterology</i> 117(6):1278-1287
	C43 WOLFF, ed., 1995, <i>Burger's Medicinal Chemistry and Drug Discovery</i> , 5 <sup>th</sup> ed:172-178, 949-982
	C44 <i>Physician's Desk Reference</i> , 2002, 56 <sup>th</sup> ed., pp. 1154-1158; 1755-1760
	C45 <i>The Merck Manual</i> , 1987, 15 <sup>th</sup> ed 1:922-924

EXAMINER	/Marcos Sznajdman/	DATE CONSIDERED	10/27/2008
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. M.S./